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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/021,407  | 12/12/2001  | Edward A. Rhad       | END-795             | 3685             |
| 27777   | 7590        | 06/13/2005           | EXAMINER            |                  |
| PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | FOREMAN, JONATHAN M |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3736                |                  |

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/021,407

Applicant(s)

RHAD ET AL.

Examiner

Jonathan ML Foreman

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△ The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-8 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-8 and 13-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

New grounds of rejection are contained within this Office Action. Accordingly this action has been made Non-Final.

#### *Claim Objections*

1. Claims 8 and 18 are objected to because of the use of "comprising" in relation with the Markush group. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). It is improper to use the term "comprising" instead of "consisting of." Ex parte Dotter, 12 USPQ 382 (Bd. App. 1931). See MPEP 2173.05(h). Appropriate correction is required.

#### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,885,561 to Cami.

In regards to claims 5 and 6, Cami discloses a thermoplastic (Col. 3, line 53) elongated substantially tubular member having a distal end (13), a proximal end (14), a longitudinal axis there between, and a side port (17; Col. 3, lines 17 - 21) on the member; a sharpened closed distal tip (Col. 3, lines 53 - 55) attached to the distal end of the tubular member having a hollow cavity filled with a material (18) which will leave an artifact (Col. 4, lines 4 - 13) spaced distally of the side port. The

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tubular member is considered to be a needle in that it is a hollow instrument for introducing material into or removing material from the body (Merriam-Webster's, 10<sup>th</sup> ed.).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5, 8, 13, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals.

In regards to claims 5, 8, 13, 14, 15 and 18, Kellogg, Jr. discloses a biopsy device (Figure 1) including an elongated substantially tubular needle having a distal end (12), a proximal end, a longitudinal axis there between, a cutter lumen (Col. 2, lines 43 - 44), a vacuum lumen (14), a side port (10b) for receiving a tissue sample (Col. 3, lines 55 - 56); a sharpened distal tip for insertion within tissue (Col. 3, lines 45 - 49), the sharpened distal tip attached to the distal end of the needle and a cutter (24) movable within the cutter lumen (Col. 2, lines 62 - 64). However, Kellogg, Jr. fails to disclose the needle being non-metallic and the distal tip having a cavity in which an artifact creating material is disposed. Van Vaals discloses a non-metallic biopsy needle (Col. 6, lines 55 - 60) including a distal tip (6; Figure 2) having a cavity in which an artifact creating material is disposed (Figure 3; Col. 6, line 61 - Col. 7, line 34). Van Vaals discloses the artifact creating material as being selected from the group of gadolinium, titanium, aluminum, copper, brass and bronze (Col. 7, lines 1 - 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy needle as disclosed by Kellogg, Jr. to be non-metallic and to include

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a distal tip having a cavity in which an artifact creating material is disposed as taught by Van Vaals in order to track the needle within the body of the patient so as to guide the needle safely through the body without damaging the tissue and to guide the needle to the desired position (Col. 2, lines 41 – 50).

6. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals as applied to claims 5 and 15 above, and further in view of U.S. Patent No. 6,272,370 to Gillies et al.

In reference to claims 6 and 16, Kellogg, Jr. in view of Van Vaals discloses an MRI compatible device comprising a needle including a non-metallic material including plastic or a ceramic material (Col. 6, lines 55 – 60). Kellogg, Jr. in view of Van Vaals fail to disclose the non-metallic material comprising a thermoplastic. However, Gillies et al. discloses an MRI compatible device formed of a non-metallic material including a thermoplastic (Col. 24, lines 17 – 19). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as disclosed by Kellogg, Jr. in view of Van Vaals of a thermoplastic as taught by Gilles et al. or any MRI compatible material as desired.

7. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals as applied to claims 5 and 15 above, and further in view of U.S. Patent No. 5,782,764 to Werne.

In reference to claims 7 and 17, Kellogg, Jr. in view of Van Vaals discloses an MRI compatible device comprising a needle including a non-metallic material including plastic or a ceramic material (Col. 6, lines 55 – 60). Kellogg, Jr. in view of Van Vaals fail to disclose the non-

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metallic material comprising a glass fiber reinforced polymer resin. However, Werne discloses an MRI compatible device including a needle comprising a glass fiber reinforced polymer resin (Col. 8, lines 36 – 65). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as disclosed by Kellogg, Jr. in view of Van Vaals of a glass fiber reinforced polymer resin as taught by Werne or any MRI compatible material as desired.

### ***Response to Arguments***

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JMLF



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